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PART II

Statutory Notifications (S.R.O.)

GOVERNMENT OF PAKISTAN
MINISTRY OF NATIONAL HEALTH SERVICES, REGULATIONS AND
COORDINATION
(Drug Regulatory Authority of Pakistan)

NOTIFICATION

Islamabad, the 9th December, 2021

S. R. O. 1582(I)/2021.— In exercise of the powers conferred by clause (a) of section 7 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) read with section 12 of the Drugs Act, 1976 (XXXI of 1976), the Drug Regulatory Authority of Pakistan with the approval of the Federal Government is pleased to fix maximum retail prices specified in column (4) of the Table below on which the drugs specified in column (2) thereof, having packing sizes specified in column (3) of that Table, shall be sold, subject to the conditions specified in paragraph 2 of this Notification namely:—

2671(1—8)

Price : Rs. 10. 00

[1748(2021)/Ex. Gaz.]

TABLE

Sr.	Drugs / Composition	Pack size	Maximum Retail Price
(1)	(2)	(3)	(4)
1.	Trezilent film coated tablet Each combo pack contains following film coated tablets: For Pack of 14 tablets each 14 Tablets of Alpelsib.....200mg 14 Tablets of Alpelsib.....50mg For Pack of 28 tablets each 28 Tablets of Alpelsib.....200mg 28 Tablets of Alpelsib.....50mg Importer: M/s Novartis Pharma (Pakistan) Limited, 15 West Wharf BLDG 1, Karachi Manufacturer: M/s Novartis Pharma Stein AG, Schaffhauserstrasse, Stein CH-4332, Switzerland Product License Holder: M/s Novartis Pharmaceuticals Corporation, 1 Health Plz, East Hanover, NJ 07936 USA	Combo pack (14 Tabs of 200mg & 14 Tabs of 50mg) Combo pack (28 Tabs of 200mg & 28 Tabs of 50mg)	Rs.74,945 Rs.146,892 (Originator Brand)
2.	Trezilent film coated tablet Each combo pack contains following tablets: For Pack of 14 tablets each 14 Tablets of Alpelsib.....150mg 14 Tablets of Alpelsib.....150mg For Pack of 28 tablets each 28 Tablets of Alpelsib.....150mg 28 Tablets of Alpelsib.....150mg Importer: M/s Novartis Pharma (Pakistan) Limited, 15 West Wharf BLDG 1, Karachi Manufacturer: M/s Novartis Pharma Stein AG, Schaffhauserstrasse, Stein CH-4332, Switzerland Product License Holder: M/s Novartis Pharmaceuticals Corporation, 1 Health Plz, East Hanover, NJ 07936 US	Combo pack (14 Tabs of 150mg & 14 Tabs of 150mg) Combo pack (28 Tabs of 150mg & 28 Tabs of 150mg)	Rs.79,354 Rs.155,534 (Originator Brand)
3.	Olumiant 4mg Tablet Each film coated tablet contains: - Baricitinib.....4mg Importer: M/s Eli Lilly Pakistan (Pvt) Ltd, 5-A, 5th floor, Al-Tijarah Centre 32-1-A, Block 6, PECHS, Main Shahra-e-Faisal, Karachi. Marketing Authorization Holder: Eli Lilly Nederland BV., Papendorpseweg 83, 3525 BJ Utrecht, The Netherlands. Manufacturer: - Manufactured by: Lilly del Caribe, Inc., 12.6Km, 65th Infantry road, Carolina, 00985 Puerto Rico. (Site also responsible for quality control) Packed and released by: Lilly S.A., Avda De la Industria 30, 28108 Alcobendas, Madrid Spain. (Site responsible for batch release in EU, Primary and Secondary Packaging).	7's 14's 28's	Rs.38,379 Rs.75,223 Rs.1,47,376 (Originator Brand)

Sr.	Drugs / Composition	Pack size	Maximum Retail Price
4.	Olumiant 2mg Tablet Each film coated tablet contains: - Baricitinib.....2mg Importer: M/s Eli Lilly Pakistan (Pvt) Ltd, 5-A, 5 th floor, Al-Tijarah Centre 32-1-A, Block 6, PECHS, Main Shahra-e-Faisal, Karachi. Marketing Authorization Holder: Eli Lilly Nederland BV., Papendorpseweg 83, 3525 BJ Utrecht, The Netherlands. Manufacturer: Manufactured by: Lilly del Caribe, Inc., 12.6Km, 65 th Infantry road, Carolina, 00985 Puerto Rico. (Site also responsible for quality control) Packed and released by: Lilly S.A., Avda De la Industria 30, 28108 Alcobendas, Madrid Spain. (Site responsible for batch release in EU, Primary and Secondary Packaging)	7's 14's 28's	Rs.38,379 Rs.75,223 Rs.1,47,376 (Originator Brand)
5.	Polivy 140mg Injection Each vial contains: Polatuzumab vedotinpiiq.....140mg Imported by: M/s Roche Pakistan Ltd., Karachi. Manufacturer: M/s BSP Pharmaceuticals SpA, Latina, Italy. Product License Holder: M/s Genentech Inc., 1 DNA Way, San Fran, CA, USA	1's	Rs.1,571,887 (Originator Brand)
6.	Rozlytrek Capsule 100mg Each capsule contains: Entrectinib.....100mg Imported by: M/s Roche Pakistan Ltd., Karachi. Manufacturer: M/s Genentech Inc., 1 DNA Way, San Fran, CA, USA. Product License Holder: M/s Genentech, Inc, USA	30's	Rs.169,831 (Originator Brand)

Sr.	Drugs / Composition	Pack size	Maximum Retail Price
7.	Rozlytrek Capsule 200mg Each capsule contains: Entrectinib.....200mg Imported by: M/s Roche Pakistan Ltd., Karachi. Manufacturer: M/s Genentech Inc., 1 DNA Way, San Fran, CA, USA. Product License Holder: M/s Genentech, Inc, USA	90's	Rs.815,188 (Originator Brand)
8.	Evrysdi for oral solution 60mg/80ml Each 1ml of reconstituted solution contains: Risdiplam.....0.75mg Imported by: M/s Roche Pakistan Ltd., Karachi. Marketing Authorization Holder: M/s Genentech, Inc. USA Manufacturer: M/s F.Hoffmann-La Roche Ltd, Switzerland	1's	Rs.1,312,434 (Originator Brand)
9.	Xofluza 40mg Film Coated Tablet Each film coated tablet contains: Baloxavir Marboxil...40mg Imported by: M/s Roche Pakistan Ltd., Karachi. Manufacturer: Shionogi & Co., Ltd. 2-5-1, Mishima, Settsu, Osaka 566-0022 Japan Marketing Authorization Holder: M/s Genentech, Inc. USA	1's	Rs.11,829 (Originator Brand)
10.	Xofluza 20mg Film Coated Tablet Each film coated tablet contains: Baloxavir Marboxil...20mg Imported by: M/s Roche Pakistan Ltd., Karachi. Manufacturer: Shionogi & Co., Ltd. 2-5-1, Mishima, Settsu, Osaka 566-0022 Japan Marketing Authorization Holder: M/s Genentech, Inc. USA	2's	Rs.12,100 (Originator Brand)

Sr.	Drugs / Composition	Pack size	Maximum Retail Price
11.	Vizimpro 30mg film coated tablet Each film coated tablet contains: Dacomitinib as monohydrate...30mg Imported by: M/s Pfizer Pakistan Limited, 12-Dockyard Road West Wharf 74000 Karachi Product License Holder: M/s Pfizer Europe MA EEIG Boulevard de la Plaine 17, 1050 Bruxelles, Belgium Manufacturer: M/s Pfizer Manufacturing Deutschland GmbH, Betriebsstätte Freiburg, Mooswaldallee 1 79090 Freiburg, Germany	30's	Rs.106,694 (Originator Brand)
12.	Tetracaine + Lidocaine Cream Each gm contains: Tetracaine.....70mg Lidocaine.....70mg	5gm 15gm	Rs.270 Rs.777
13.	Apremilast Tablet 30mg Each film coated tablet contains: Apremilast.....30mg	4x14's	Rs.3,559
14.	Ertugliflozin L-Pyrogutamic Acid eq to Ertugliflozin 5mg Tablet Each film coated tablet contains: - Ertugliflozin L-Pyrogutamic Acid eq to Ertugliflozin..... 5mg	30's 28's 20's 14's 10's	Rs.2,020 Rs.1,885 Rs.1,347 Rs.942 Rs.673
15.	Ertugliflozin L-Pyrogutamic Acid eq to Ertugliflozin 15mg tablet Each film coated tablet contains: - Ertugliflozin L-Pyrogutamic Acid eq to Ertugliflozin..... 15mg	30's 28's 20's 14's 10's	Rs.2,271 Rs.2,120 Rs.1,514 Rs.1,060 Rs.757
16.	Ipratropium bromide as monohydrate 0.025% w/v Respule 1 ml Each 1ml contains: Ipratropium bromide as monohydrate... 0.025%	5's x 1ml	Rs.208
17.	Cefuroxime Sodium Dry Powder for Injection 750mg / Vial Each Vialcontains: Cefuroxime Sodium..... 750mg	Vial	Rs.82
18.	Cefuroxime Sodium Dry Powder for Injection 1.5gm / Vial Each vial contains: Cefuroxime Sodium..... 1.5gm	Vial	Rs.136
19.	Chloroquine Phosphate 250mg/5ml Injection Each 5ml contains: - Chloroquine Phosphate250mg	100x5ml	Rs.301

Sr.	Drugs / Composition	Pack size	Maximum Retail Price
20.	Lactitol Monohydrate 667mg/ml Syrup Each ml of Syrup contains: - Lactitol Monohydrate667mg	120ml 90ml 60ml	Rs.333 Rs.250 Rs.166
21.	Lopinavir 100mg+ Ritonavir 25mg Tablet Each film coated tablet contains: - Lopinavir..... 100mg Ritonavir..... 25mg	120's	Rs.6,341
22.	Paracetamol + Diphenhydramine + Phenylephrine Tablet Each film coated tablet contains: Paracetamol BP.....325mg Diphenhydramine HCl BP.....25mg Phenylephrine HCl BP.....5mg	100's	Rs.810
23.	Tacrolimus Ointment 0.03% Each gram contains: Tacrolimus as monohydrate....0.3mg	5gm	Rs.14
24.	Imatinib 400mg Capsule Each capsule contains: Imatinib (as mesylate) 400mg	10's 30's 60's 90's 120's	Rs.16,500 Rs.47,520 Rs.95,040 Rs.142,560 Rs.190,080
25.	Fluorouracil Injection 1000mg /20ml Each 20ml vial contains:- 5-Fluorouracil1000mg	1x20ml	Rs.297
26.	Deflazacort Tablets 30mg Each Tablet Contains: Deflazacort..... 30mg	10's 20's 30's	Rs.692 Rs.1,356 Rs.1,993
27.	Ertugliflozin L-Pyrogutamic Acid eq to Ertugliflozin 5mg +Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 5mg/100mg tablet Each film coated tablet contains: - Ertugliflozin L-Pyrogutamic Acid eq to Ertugliflozin..... 5mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg	10's 14's 20's 28's 30's	Rs.1,523 Rs.2,985 Rs.2,132 Rs.4,179 Rs.4,386
28.	Ertugliflozin L-Pyrogutamic Acid eq to Ertugliflozin 15mg +Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 15mg/100mg tablet Each film coated tablet contains: - Ertugliflozin L-Pyrogutamic Acid eq to Ertugliflozin..... 15mg Sitagliptin Phosphate Monohydrate eq. to Sitagliptin 100mg	10's 14's 20's 28's 30's	Rs.1,603 Rs.3,143 Rs.2,245 Rs.3,771 Rs.4,618

Sr.	Drugs / Composition	Pack size	Maximum Retail Price
29.	Varicella Vaccine Inj. Each dose of 0.5ml of reconstituted vaccine contains: Live attenuated varicella zoster virus (virus strain:Oka/SK, cell line:MRC-5) $\geq 2,400$ PFU Ph.Eur.Specifications Diluent: Water for injection0.7ml/vial.	One 0.5ml vial+one vial of diluent (WFI) Box of 5 vials+5 diluents of single dose	Rs.2,105 Rs.10,100
30.	Indacaterol 110mcg + Glycopyrronium 50mcg DPI Capsule Each capsule contains: Indacaterol (as maleate)..... 110mcg Glycopyrronium (as bromide)....50mcg Each delivered dose contains: Indacaterol (as Maleate).....85mcg Glycopyrronium (as bromide)....43mcg	30's	Rs.4,350
31.	Brinzolamide + Timolol (As maleate) Ophthalmic Suspension Each ml of suspension contains:- Brinzolamide.....10mg Timolol (as timolol maleate).....5mg	5ml	Rs.630
32.	Cabazitaxel 60mg/1.5ml Injection Each injection vial contains: Cabazitaxel (anhydrous) 60mg Polysorbate 80 q.s. 1.5ml Each diluent vial contains: Ethanol 13% (w/w) in water for injection 4.5ml	1 vial of 1.5ml	Rs.176,555
33.	Pazopanib 200mg tablet Each film coated tablet contains: Pazopanib (as hydrochloride)200mg	30's	Rs.53,874
34.	Pazopanib 400mg tablet Each film coated tablet contains: Pazopanib (as hydrochloride)400mg	30's	Rs.87,347
35.	Levonorgestrel 75mg Implant Each implants (rod) contains:- Levonorgestrel.....75mg	1's (each implant contains 2 rods of 75mg levonorgestrel) 10's 10 Implants (each implant contains 2 rods of 75mg levonorgestrel)	Rs.1,157 Rs.11,107

Sr.	Drugs / Composition	Pack size	Maximum Retail Price
36.	Amidotrizoate meglumine 76% Injections Each ml Contains: Amidotrizoate meglumine.....660mg Sodium amidotrizoate..100mg	20ml 50ml 100ml	Rs.248 Rs.607 Rs.1,189
37.	Formoterol Fumarate Dihydrate + Budesonide Inhaler Formoterol Fumarate Dihydrate 12mcg Budesonide 400mcg Discair Inhalation Powder	60 doses	Rs.707
38.	Formoterol Fumarate Dihydrate + Budesonide Inhaler Formoterol Fumarate Dihydrate 12mcg Budesonide 200mcg Discair Inhalation Powder	60 doses	Rs.604

2. The maximum retail price (MRP) shall be subject to the following conditions, namely:—

- manufacturers and importers of drug shall furnish MRP of the drug to the Division of Costing and Pricing of the Drug Regulatory Authority of Pakistan;
- the MRP shall be printed on the label in the manner prescribed by the Drugs (Labeling and Packing) Rules, 1986; and
- the MRP as mentioned in column (4) of the above Table shall not be applicable on drugs registrations of which under sub-rule (4) of rule 29 of the Dugs (Licensing, Registration and Advertising) Rules, 1976 were issued before the issuance of this Notification, unless otherwise stated expressly.

[No.F.11-23/2021-DD(P).]

AAMAR LATIF,
Deputy Director (Legal Affairs).